

JUL - 9 2009

510(k) summary

REFRESH® OPTIVE™ Contacts Lubricating and Rewetting Drops

July 2009

1. Applicant Information

Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612-1599
Contact Person: Joanne Lemmo
Telephone No.: (714) 246-5844
Fax No.: (714) 246-4051
E-mail: lemmo_joanne@allergan.com

2. Device Information

Classification names: Soft (hydrophilic) Contact Lens Care Products and
Rigid Gas Permeable Contact Lens Care Products
Device classification: Class II
Regulation numbers: 21 CFR 886.5928 and 21 CFR 886.5918
Product codes: LPN & MRC
Proprietary name: REFRESH® OPTIVE™ Contacts Lubricating and
Rewetting Drops

3. Predicate Device

The predicate device is Allergan REFRESH® Contacts Lubricating and Rewetting Drops which was cleared under K992028.

4. Description of device

REFRESH® OPTIVE™ Contacts Lubricating and Rewetting Drops is a sterile, buffered, isotonic, preserved solution. This aqueous formulation includes carboxymethylcellulose sodium, glycerin, boric acid, calcium chloride dihydrate, erythritol, levocarnitine, magnesium chloride hexahydrate, potassium chloride, purified water, PURITE® (stabilized oxychloro complex), sodium borate decahydrate, and sodium citrate dihydrate. This formula does not contain chlorhexidine, thimerosal, or any other mercury-containing ingredients.

5. Indications for use

Use REFRESH® OPTIVE™ Contacts Lubricating and Rewetting Drops to lubricate and rewet soft and rigid gas permeable (RGP) contact lenses, to help relieve dryness, discomfort, and irritation that may be associated with lens wear and to cushion lenses by placing a drop on the lens prior to insertion on the eye.

6. Substantial Equivalence

The claim of substantial equivalence to Allergan REFRESH® Contacts Lubricating and Rewetting Drops is based on the indication for use as a lubricating and rewetting solution for soft (hydrophilic) and RGP contact lenses. REFRESH® OPTIVE™ Contacts Lubricating and Rewetting Drops and REFRESH® Contacts Lubricating and Rewetting Drops both contain sodium carboxymethylcellulose as an active ingredient and both formulas are preserved with PURITE® (a stabilized oxychloro complex).

The sponsor performed stability, compatibility, toxicology and microbiology testing and a clinical study with this formulation to support the claim of substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Allergan, Inc.
c/o Beverley Venuti, PhD., RAC
Foresight Regulatory Strategies, Inc.
187 Ballardvale St.
Suite 180
Wilmington, MA 01887-4461

Re: K083812

Trade/Device Name: REFRESH OPTIVE™ Contacts Lubricating and Rewetting Drops

Regulation Number: 21 CFR 886.5928

Regulation Name: Soft (hydrophilic) contact lens care products

Regulatory Class: Class II

Product Code: LPN, MRC

Dated: June 30, 2009

Received: July 2, 2009

Dear Dr. Venuti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Malvina B. Eydelman for".

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083812

Device Name: REFRESH® OPTIVE™ Contacts Lubricating and Rewetting Drops

Indications for Use:

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Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K083812